K000079

FEB 4 2000

510(k) Summary

SUBMITTED ON BEHALF OF:

Company Name:	Nikomed U.S.A., Inc.
Address:	206 Airport Blvd. Doylestown, PA 18901
Telephone:	215-230-8455
Fax:	215-230-8446

by:	**Elaine Duncan, M.S.M.E., RAC** President, Paladin Medical®, Inc. PO Box 560 Stillwater, MN 55082
Telephone:	715-549-6035
Fax:	715-549-5380

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **January 10, 2000**

TRADE NAME: **Nikopad Electrosurgical Grounding Pad Model 4777M**

COMMON NAME: **Electrosurgical Grounding Pad**

SUBSTANTIALLY EQUIVALENT TO:
K993302 – Nikopad* Electrosurgical Grounding Pad (*or sold under various commercial names)

DESCRIPTION of the DEVICE:
The Nikopad Electrosurgical Grounding Pad Model 4777M is a flexible, conductive adhesive electrosurgical grounding pad with integrated 100 cm cable terminating in a 4 mm shrouded safety plug to mate wit hHirshmann product. The conductive area is 192.50 sq cm and the adhesive area is 292 sq cm. Units are packaged individually and typically sold 25 pieces to a box.

INDICATIONS FOR USE:
The Nikomed USA electrosurgical grounding pad (sold under various commercial names through repackagers and resellers) is indicated for use with electrosurgical generators for cutting and coagulation.

SUMMARY of TESTING:
Biocompatibility testing consistent with the ISO 10993-1, recommended material evaluations for acute (less than 24-hour) intact skin contacting devices. The materials passed all screens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Nikomed U.S.A., Inc.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K000079
Trade Name: Nikomed Electrosurgical Grounding Pad Model 4777M
Regulatory Class: II
Product Code: HAM, GEI
Dated: January 10, 2000
Received: January 11, 2000

Dear Ms. Duncan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K000079

Device Name: Nikomed Electrosurgical Grounding Pad Model 4777M

Indications for Use:

The Nikomed USA electrosurgical grounding pad (sold under various commercial names through repackagers and resellers) is indicated for use with electrosurgical generators for cutting and coagulation.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000079